87-498

No. ———

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED

Under Section 262 of the Public Health Service Act, private manufacturers cannot produce, manufacture or sell biologic products, including poliovirus vaccines, without a federal license. Section 262(d) of the Act provides that a license may be issued by the regulating agency "only upon a showing that the . . . products . . . meet standards . . . prescribed in regulations."

The questions presented are:

I. Is the view of the Third or of the Eighth and Ninth Circuits correct regarding whether employees of the regulating agency under § 262 have discretionary power to license a biologic product which does not comply with the agency's safety regulations?

II. After *Varig*, does the discretionary function exception bar an FTCA action alleging that a federal employee knowingly violated the agency's own safety regulations?

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

The petitioners Kevan Berkovitz, a minor, by his parents and natural guardians Arthur Berkovitz, his wife, Donna Berkovitz, and Arthur Berkovitz and Donna Berkovitz, in their own right, respectfully pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Third Circuit, entered in the above-entitled proceeding on June 30, 1987.

OPINIONS BELOW

The opinion of the Court of Appeals for the Third Circuit is reported at 822 F.2d 1322 and is reprinted in the appendix, p. 1a, *infra.*

The opinion of the United States District Court for the Western District of Pennsylvania (Diamond, D.J.)

has not been reported. It is reprinted in the appendix, p. 28a, *infra.*

JURISDICTION

Invoking federal question jurisdiction, Petitioners brought this Federal Tort Claims suit against the United States in the Western District of Pennsylvania. The government filed a Motion to Dismiss or in the Alternative for Summary Judgment, asserting that the challenged conduct was discretionary and that pursuant to 28 U.S.C. § 2680(a), the court did not have subject matter jurisdiction to hear the claims. The motion was denied. On June 5, 1986, the District Court certified the question for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). On July 21, 1986, the Third Circuit entered an order accepting the appeal.

On appeal, the Third Circuit entered a judgment and opinion reversing the District Court's order and directing that the government's motion for summary judgment be granted. The judgment of the Court of Appeals was entered on June 30, 1987. Berkovitz' petition for rehearing or rehearing en banc was denied on July 22, 1987, with three judges indicating they would grant rehearing en banc. This petition was filed within ninety days thereafter.

The jurisdiction of this Court to review the judgment of the Third Circuit is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

Section 262(d) of the Public Health Service Act is reprinted in the appendix, p. 41a, *infra.*

STATEMENT OF THE CASE

On May 10, 1979, Kevan Berkovitz was given a dose of polio vaccine by his pediatrician in Charleroi, Pennsylvania. One month later, he contracted paralytic poliomyelitis. He was not yet three months old. The Com-

municable Disease Center, a United States agency, determined that Kevan's polio was caused by the live-virus vaccine he ingested, which had been licensed and approved for release by the federal government. Petitioners assert liability based on the government's conduct in licensing the vaccine for production and release, despite its known failure to comply with regulatory safety standards.

In 1944, Congress recognized that the unregulated use of biologic products, including live-virus vaccines, could present epidemic risks to the public health. Congress therefore directed that biologic products could not be produced or distributed by private manufacturers without a federal license. 42 U.S.C. § 262(a). The Department of Health and Human Services, through its Division of Biologic Standards (DBS), was empowered by Congress to issue a license:

> . . . only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. Licenses shall be issued, suspended, and revoked as prescribed by regulations.

42 U.S.C. § 262(d). The regulations similarly provide that a product license shall be issued "only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations." 21 C.F.R. § 601.20(a).[1]

In 1963, DBS issued a license for an attenuated live poliovirus strain which had been developed by Dr. Albert Sabin and tested in the Soviet Union. The regulation which was "designed to insure the continued safety, purity and potency" of original virus strains is found at

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[1] These regulations were formerly at 42 C.F.R. § 63.110, *et seq.*

21 C.F.R. § 630.10(b)(i)(2). The first allegation of Petitioner's Complaint is that the Sabin strain was not tested in accordance with these regulations, that its deficiencies were known to the agency prior to the issuance of the license, and that agency employees acted without lawful authority in issuing a license for this non-complying biologic product. Complaint ¶ 17(b), (c).

A product license is also required for each production seed virus, derived from a "passage" or replication of the original virus strain and used to manufacture vaccine monopools. Regulations prescribe the tests which must be performed by the manufacturer to assess the neurovirulence and genetic stability of the seed virus. Regulations also prescribe the results which must be objectively demonstrated before the seed can be licensed for vaccine production. As noted *supra*, DBS is empowered to issue the license only upon "examination of the product and upon a determination that the product complies with the standards prescribed in the regulations." 21 C.F.R. § 601.20(a).

Among the production seeds derived from the Sabin strain was a virus designated "45 B 85". This seed virus had not been subjected by the manufacturer to all required testing and had failed some of the tests which were performed. The second allegation of Petitioners' Complaint is that agency employees acted without lawful authority in licensing 45 B 85 for vaccine production, in the absence of the required showing that the virus had been subject to all required testing and complied with all regulatory standards.[2] Complaint ¶¶ 17(d), (e), (g), (h).

[2] Petitioners' counsel represent Plaintiffs in two other pending polio vaccine cases: *Parulski v. United States*, Civil Action No. 87-0731 (M.D. Pa.) and *Kaye v. United States*, Civil Action No. C2-86-1002 (S.D. Ohio). The vaccine administered in each of these cases was also derived from 45 B 85.

The final allegation of Petitioners' Complaint is that the Bureau of Biologics (DBS' successor agency) exercised its regulatory authority to test vaccine lots prior to release; that the agency employee who reviewed the test results knew that a vaccine lot, derived from 45 B 85 and containing Kevan's dose, was excessively neurovirulent; and that issuance of a lot release approval permitting the vaccine to be distributed to the public was improper.[3] Complaint ¶ 19(a), (b).

At each step of this process, an agency employee unlocked a door which had been closed by Congress. As the result of his ingestion of the vaccine thus produced, Kevan Berkovitz has been paralyzed in all of his limbs and suffers a severe scoliosis, or curvature, of his spine. His muscles have atrophied and contracted, pulling his limbs into a deforming posture. Because his paralysis prevents him from breathing, a tracheostomy was performed, cutting a hole in his throat through which he is maintained on a respirator. His injuries are permanent. Complaint ¶¶ 23, 24.

REASONS FOR GRANTING THE WRIT

I. There exists an irreconcilable conflict among the Third, Eighth and Ninth Circuit Courts of Appeals on the questions presented.

The opinion of the Third Circuit in this case is in direct conflict with *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987) and *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982), both polio vaccine cases. The divergence is a direct result of this Court's opinion in *U.S. v. S.A. Empresa de*

[3] Under 21 C.F.R. § 610.2(a), the agency may do its own confirmatory testing before issuing a lot release approval. Plaintiffs aver that both the manufacturer's and the agency's testing indicated that the lot in question was excessively neurovirulent. This section does not apply to the licensing of the strain and seed virus.

Viacao Aerea Rio Grandense, 467 U.S. 797, 104 S.Ct. 2755, 81 L.Ed.2d 660 (1984), hereafter *Varig*.

Prior to *Varig*, there was uniformity among the circuits in construing the duties of government under § 262. In *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), the court held that § 262 imposed mandatory obligations on the regulating agency and that the agency's issuance of a lot release approval for an excessively neurovirulent vaccine was not protected conduct:

> [N]o discretion was conferred to disregard the mandatory regulatory command . . . Although Congress has provided that activity within the authority of a government official, if a 'discretionary function' may not be the basis of Government liability even if negligent or an abuse of discretion, Congress has not immunized such activity of it exceeds the authority conferred. Liability, in such cases, in predicated not on a negligent or unwise policy determination, but on the failure of Government employees to conform to and act consistently with the authority delegated.

Id. at 1069.

Similarly, in *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982), the Eighth Circuit held that:

> The Secretary has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public.

Id. at 1273.

Varig followed in 1984. Plaintiffs in *Varig* were injured when a trash receptacle in a commercial airliner caught fire. Plaintiffs first challenged the decision of the Secretary of Transportation to implement only a "spot-check" inspection system to monitor airline compliance with FAA regulations. The action of the Secretary in

choosing the spot-check system was found to be fully within her express statutory power[4] and therefore immune. *Varig*, *supra*, 104 S.Ct. at 2766. Plaintiffs also challenged the FAA's failure to inspect the aircraft in question. On this point, the Court held that "acts of FAA employees in executing the 'spot-check' program in accordance with agency directives are protected by the discretionary function exception as well." *Ibid.*

The distinctions between *Varig* and the case at bar are significant. For example, the FAA was expressly empowered by 49 U.S.C. § 1421(c) to "grant exemption from the requirements of any rule or regulation . . . if [the Administrator] finds that such action would be in the public interest". The regulations do not require a showing of regulatory compliance before the issuance of a certificate, so long as the Administrator finds that any regulatory deficiencies are compensated for by "other factors." Further, the FAA is expressly empowered to vary compliance monitoring "according to the circumstances" and to take "calculated risks" in administering the spot-check system. *Id.* at 2768-69.

By contrast, the statute and regulations here provide that the agency may issue a license *only* upon a showing that the product meets regulatory standards. Nowhere in the enabling legislation or regulations is the agency given the discretion to exempt live-virus vaccines from the requirements of the regulations. Nowhere do the regulations empower the agency to relax scrutiny of test data "according to the circumstances" or to take "calculated risks" regarding the safety of vaccine recipients. Unlike the FAA inspectors in *Varig*, the agency em-

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[4] 49 U.S.C. § 1421(a)(3)(c) specifically empowers the Administrator to prescribe reasonable regulations governing inspection of aircraft and "in the discretion of the Administrator, the period for, and the manner in, which such inspection . . . shall be made."

ployees here were acting *outside* the scope of express statutory and regulatory directives.[5]

These distinctions were disregarded, in an apparent attempt to defer to the Court's statement in *Varig* that whatever else the discretionary functon exception may include, "it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." *Id.* at 2767.

We respectfully submit that it was this seeming intent to extend broad protection to regulatory conduct that impelled the panel majority here to overrule *Griffin*,[6] and troubled the Ninth Circuit in *Baker* with what had become a "close and difficult" question. *Baker v. United States, supra*, 817 F.2d at 564.

The panel majority in *Berkovitz* struggled to conform to the *result* reached in *Varig*, but did so only at the expense of a consistent rationale. The majority first addressed the government's argument that *Varig* provided a *per se* immunity for regulatory conduct.[7] Although

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[5] In *Red Lake Band of Chippewa Indians v. United States*, 800 F.2d 1187 (D.C. Cir. 1986), Judge Bork wrote that:

> A decision cannot be shielded from liability if the decision-maker is acting without actual authority. A government official has no discretion to violate the binding laws regulations or policies that define the extent of his [or her] official powers. An employee of the government acting beyond his [or her] authority is not exercising the sort of discretion the discretionary function exception was enacted to protect. This proposition is implied in *Varig* and *Dalehite* and has been uniformly followed.

Id. at 1196.

[6] *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974).

[7] See discussion, *infra*, at 11.

this argument was rejected, the majority had difficulty discerning what limits had been established by the case.

Berkovitz argued that agency employees do not have discretion to disregard mandatory commands in the agency's enabling statute and regulations and that Congress did not intend the discretionary function exception to immunize the disobedience of the Executive to an express legislative command.

The majority's response was to construe the statute and the regulations as non-mandatory, i.e., as conferring power to license *despite* regulatory non-compliance. If this language can be construed as non-mandatory, if the word "only" can be read by a court to mean "occasionally", then there is no way for Congress to command the obedience of a regulatory agency. The opinion thus accomplishes a *per se* protection for regulatory conduct, even while acknowledging that Congress did not intend such a result in enacting § 2680(a).[8]

In dissent, Presiding Judge Higginbotham wrote that the majority's analysis "disregards the clear command of federal law" expressed in § 262 (24a); "distorts" the discretionary function exception (26a); and "expand[s] the exception beyond the boundaries of any case reported to date" (23a).

The Ninth Circuit, construing the same statute and regulations and also employing *Varig* as its "map", reached the opposite result, concluding that the licensing of a non-compliance polio vaccine is not protected conduct:

> The government argues that the regulatory scheme in this case is similar to the scheme in *Varig*, and that the regulations being enforced in *Varig* were no less mandatory than those at issue here. How-

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[8] 28 U.S.C. § 2680(a), setting forth the discretionary function exception.

> ever, the government overlooks an important distinction. In *Varig*, the mandatory regulations govern the conduct of the airline, not the government . . . In this case the Secretary may not issue a license for manufacturing polio virus vaccine unless the relevant test data has been submitted . . . *Agency employees charged with enforcing polio virus vaccine safety standards must require the submission of the test data. As to that there is no discretion.*

Baker v. United States, *supra*, 817 F.2d at 566 (emphasis added). We respectfully submit that the analysis of the Ninth Circuit is correct.

The Third Circuit has misconstrued *Varig* and, in doing so, rendered a judgment that is inconsistent with this Court's historic regard for Congress' power to prescribe the obligations of administrative agencies. One example is the caveat added by (now) Chief Justice Rehnquist to his opinion in *Heckler v. Chaney*, —— U.S. ——, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985), observing that in protecting discretionary activity from judicial review under the Administrative Procedure Act, "Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers." *Id.*, 105 S.Ct. at 1657. The Court has consistently held that an agency may not, by regulation or otherwise, abridge or diminish the rights, duties and obligations defined by Congress. *Campbell v. United States*, 107 U.S. 407 (1882); *Federal Election Committee v. Democratic Senatorial Campaign Committee*, 454 U.S. 27, 32-33, 102 S.Ct. 38, 42, 70 L.Ed.2d 23 (1981).

The conflict between *Baker* and *Berkovitz* is stark; it is irreconcilable; and it calls into question the proper balance of power between Congress and the Executive in regulatory matters. If unresolved, it will continue to confound trial courts confronted with discretionary function cases, and the analytical rifts will only widen.[9] The issue therefore warrants review by this Court to insure uniformity of judgment among the federal courts.

II. The issues presented are of exceptional importance in defining what measure of agency accountability under the FTCA, if any, remains after Varig.

It is the position of the United States government that *Varig* extends the immunity of the discretionary function exception to *all* regulatory conduct. That position has been asserted of record in this case and in others involving the exception,[10] and will continue to be asserted by the government in regulatory cases. With the opinion in *Berkovitz*, the government has accomplished the functional equivalent of a *per se* rule.

It is respectfully submitted that if *Varig* did intend to sweep so broadly and to protect all regulatory conduct, the Court's extensive discussion of the underlying statutory and regulatory bases for the agency's conduct would have been superfluous. Moreover, such a reading is not supported by the language of 28 U.S.C. § 2680(a), defining the exception. If Congress had intended to protect all regulatory acts, they could very easily have done so. The statute would simply have read: "All activities of federal regulatory agencies are exempt." The words "discretionary function" would have been unnecessary. The purposeful use of these words indicates that Congress' intent was to protect only the exercise of express discretionary *power*.

If there are limits to *Varig*—if there is still a category of regulatory conduct for which the government may be

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[9] Motions to Dismiss are pending in the polio cases cited *supra* at note 2. The *Parulski* motion has been stayed pending the Court's response to this petition. The *Kaye* motion, which was filed on October 30, 1986, remains pending.

[10] *E.g.*, *Collins v. United States*, 783 F.2d 1225 (5th Cir. 1986).

held accountable—we respectfully submit that the Court should take this opportunity to define them, and to put to rest the government's claim of *per se* regulatory immunity.

The case presented here would be a good prism for refraction and analysis of the issue. The questions are narrowly drawn: (1) do the statute and regulations confer discretionary power to license non-complying biologic products; and (2) is agency conduct which exceeds the scope of express statutory and regulatory authority protected? Further, the statutory and regulatory language is straightforward; and the factual record is limited to the allegations of the complaint, which must be accepted as true.

This case is also significant because it has called into question the duties of government with respect to regulation of biologic products. Such products, including live-virus vaccines and organisms created by genetic manipulation, can present epidemic risks to the public health. One poliovirus monopool generates one million doses of live-virus vaccine, capable of producing contagious and morbid disease in the adults and healthy school children who are required to take it. That is precisely why Congress directed that biologic products cannot be licensed unless they are demonstrated to meet objective regulatory standards designed to insure their continued safety. There may not be another section in all of the U.S. Code that imposes so stringent a duty on the regulating agency.

The decision below sets agency employees free to disregard congressional intent and objective regulatory standards and to act instead according to their own subjective judgment of the more expedient course. Exceptional importance attaches to this decision, not only because it jeopardizes the proper and uniform administration of federal law, but also because of the broad potential for harm inherent in the release of defective biologic products.

CONCLUSION

For the reasons stated above, Petitioners Kevan Berkovitz, and Arthur and Donna Berkovitz, his parents, respectfully request this Honorable Court to grant their Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 86-3444

KEVAN BERKOVITZ, a minor by his parents and natural guardians ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right

v.

UNITED STATES OF AMERICA,
Appellant

On Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. Civil No. 84-2893)

Argued February 19, 1987

BEFORE: HIGGINBOTHAM and SLOVITER,
Circuit Judges,
and ROTH, *District Judge**

(Opinion Filed June 30, 1987)

---

* Honorable Jane R. Roth, United States District Court for the District of Delaware, sitting by designation.

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OPINION OF THE COURT

SLOVITER, *Circuit Judge.*

I.

Issue

In *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), this court held that a suit alleging negligence on the part of the Division of Biologic Standards (DBS) in approving for production and distribution a polio vaccine which subsequently caused the plaintiff's paralysis was not barred by the discretionary function exception to United States liability under the Federal Tort Claims Act (FTCA). In *United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984), the Supreme Court held that the discretionary function exception barred an FTCA suit based on the negligence of the Federal Aviation Administration (FAA) in certifying an aircraft that did not comply with applicable safety regulations. The FTCA action before us makes allegations of government negligence virtually indistinguishable from those asserted in *Griffin*. The question before us on this interlocutory appeal is whether our holding in *Griffin* remains binding following the Supreme Court's pronouncement in *Varig* on the scope of the discretionary function exception.

II.

Facts

The government sought and was granted certification pursuant to 28 U.S.C. § 1292(b) of the district court's order denying its motion to dismiss this action for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). The district court was obliged to accept the

factual averments of the complaint as true for purposes of the motion. *See Curtis v. Everette*, 489 F.2d 516, 518 (3d Cir. 1973), *cert. denied*, 416 U.S. 995 (1974). Our review is plenary. Berkovitz's amended complaint alleges the following facts.

Kevan Berkovitz, a minor, received a dose of Orimune, a Sabin Oral Poliomyelitis Vaccine manufactured by Lederle Laboratories (Lederle), on May 10, 1979 and contracted paralytic poliomyelitis within a month. The Communicable Disease Center, a United States agency, determined that Berkovitz had contracted polio from the vaccine.

Prior to 1972, the Division of Biologic Standards (DBS), a division of the National Institutes of Health, licensed Lederle to produce a trivalent oral vaccine using live virus of the Sabin strains. Lederle then developed from the original Sabin strains a seed virus which DBS licensed it to produce despite the fact that it did not satisfy standards for neurovirulence set forth in the regulations applicable to live polio vaccines. After 1972, a division of the Food and Drug Administration (FDA) took over responsibility for approval and licensure of live polio vaccines. The FDA approved a monopool of virus [1] developed from the defective seed virus for use in production despite the fact that the monopool was tested and found to exceed the applicable standards for neurovirulence. This defective monopool was subsequently used by Lederle in the manufacture of the lot of trivalent oral polio vaccine, Orimune, administered to Berkovitz.[2]

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[1] There are three types of the Sabin strains of poliovirus: Types I, II and III. A monopool is a single type. When monopools of the three types are combined, they form a trivalent vaccine.

[2] Although the government contends that it followed all mandatory regulations in licensing Lederle to produce Orimune and in approving for production and release the lot of vaccine administered to Berkovitz, it agrees that for purposes of this appeal, we must assume Berkovitz's allegations of negligence to be true. Appellant's Brief at 4 n.3.

Berkovitz (joined by his parents as his guardians) filed a complaint in federal district court, after following the requisite administrative procedure. The complaint asserts a claim against the United States under the Federal Tort Claims Act for the negligence of DBS in licensing and of the FDA in approving for release the live polio vaccines.[3] Specifically, Berkovitz alleges that he suffered damages as a result of: 1) the negligence of DBS in licensing Lederle for the original Sabin strains; 2) the negligence of the FDA in approving for production and release the lot of trivalent vaccine manufactured from the defective monopool; 3) the negligence of the FDA in failing to withdraw the defective vaccine from the market; and 4) the negligence of the FDA in failing to require Lederle to warn of the risks of the defective vaccine.

The government moved for dismissal for lack of subject matter jurisdiction on the grounds that the agency actions challenged fall within the discretionary function exception to the United States' waiver of sovereign immunity under the FTCA. In ruling on the government's motion, the district court relied on this court's prior decision in *Griffin*:

> In *Griffin*, the plaintiff sustained personal injuries resulting from the ingestion of a [vaccine] which did not conform to the defendant's regulations. The Third Circuit concluded that the government was not immune from suit pursuant to the discretionary function exception . . . since the government employee's conduct in implementing agency regulations required only scientific evaluation and not the formulation of policy.

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[3] Berkovitz also initiated an action against Lederle. That action was settled.

App. at 51-52. The court rejected the government's argument that the *Griffin* holding does not survive the Supreme Court's subsequent decision in *Varig*. The district court stated that under Third Circuit Internal Operating Procedure 8.C., "no matter how persuasive the arguments may be that *Griffin* is no longer valid, we are bound to apply the principles in *Griffin*." App. at 55. Applying those principles, the court concluded that the discretionary function exception barred Berkovitz's claims of "alleged failure to warn and withdraw the product" but did not bar Berkovitz's claims of "negligent licensure and approval" of either the original Sabin strains or the lot of vaccine administered to Berkovitz. App. at 56.[4]

III.

The Legal Background: Griffin *and* Varig

Under the FTCA, the United States waives its sovereign immunity from suit for compensatory damages for personal injury resulting from the conduct of a government employee acting within the scope of his employment. 28 U.S.C. §§ 1346(b), 2674. One of the exceptions to which that waiver is subject provides that the United States does not waive its sovereign immunity from actions "based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty." 28 U.S.C. § 2680(a). We have treated the discretionary function exception as establishing a jurisdictional bar. *See Smith v. Johns-Manville Corp.*, 795 F.2d 301, 306 n.8 (3d Cir. 1986); *Gibson v. United States*, 457 F.2d 1391, 1392 n.1 (3d Cir. 1972). The government contends that Berkovitz's action falls within the discretionary function exception and is barred by the United States' sovereign immunity.

[4] On appeal, Berkovitz concedes that his claims for negligent failure to warn or withdraw are barred by the discretionary function exception. Appellee's Brief at 3.

Reading Berkovitz's complaint in the way most favorable to Berkovitz, it is clear that, at least in part, Berkovitz alleges a violation of regulations identical to those at issue in *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974). Griffin, who had contracted polio after ingesting a Sabin type polio vaccine, sued the United States alleging DBS negligence in releasing the vaccine at issue. At that time, as now, agency regulations allowed release of vaccine only if, after a "comparative evaluation" of five criteria with a reference strain of vaccine, "a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference . . . ." *Id.* at 1062-63 n.7 (quoting 42 C.F.R. § 73.114(b)(1)(iii) (1974) (now codified at 21 C.F.R. § 630.16(b)(1)(iii) (1987))). Tests performed by DBS indicated that the vaccine at issue displayed greater neurovirulence than the reference on all five enumerated criteria. *Id.* at 1067 & n.18. Griffin contended that DBS could be held liable for its release of the vaccine in violation of its own regulations. The government contended both that the decision to release the lot of vaccine in question involved the exercise of a discretionary function and that "Congress intended, by the discretionary function exception . . ., to exclude all claims 'arising from acts of a regulatory nature.'" *Id.* at 1063.

We noted that "accepting the Government's [latter] contention would effectively immunize all Governmental activity from judicial review except the most ministerial acts." *Id.* at 1063-64. Instead we construed the decision in *Dalehite v. United States*, 346 U.S. 15 (1953), as limiting, the discretionary function exception to activity involving "considerations of public policy", 500 F.2d at 1064, focusing on the Court's statement in *Dalehite* that "[w]here there is room for policy judgment and decision, there is discretion." 346 U.S. at 36 (quoted in 500 F.2d at 1064).

Although we accepted DBS' construction of its regulations as allowing "judgmental determination as to the degree to which each of the enumerated criteria indicated neurovirulence in monkeys," we concluded that this was "a scientific, but not policy-making, determination." 500 F.2d at 1066. We pointed out that "responsibility was limited to merely executing the policy judgments of the Surgeon General." *Id.*

For this reason, we concluded that DBS' discretion in "performance of scientific evaluation" did not justify immunization from judicial review. *Id.* Moreover, we noted that DBS had no discretion "to disregard the mandatory regulatory command" under the "biological variation" rubric that it had applied and that DBS had exceeded its authority under the regulations by "discounting test results that were required to be considered significant." *Id.* at 1068. We concluded:

> We do not hold that the Government may be liable for policy determinations made by its officials. Rather, we hold only that the Government may be liable where its employees, in carrying out their duties, fail to conform to pre-existing statutory and regulatory requirements.

Id. at 1069.

In this case, Berkovitz's complaint alleges a failure by the government to insure Lederle's compliance with "applicable reguluations, including, but not limited to: . . . 42 C.F.R. 73.114(b)(1)(iii)," App. at 29, the same regulation at issue in *Griffin*. Thus, if we are still bound by our holding in *Griffin* that release of a vaccine lot that does not satisfy regulatory criteria is not a discretionary function, Berkovitz's action under the FTCA may be maintained. *See* Internal Operating Procedures of the Court of Appeals for the Third Circuit, Chapter 8.C., discussed in *Poulis v. State Farm Fire & Casualty Co.*, 747 F.2d 863, 867 (3d Cir. 1984). On the other hand,

if an intervening Supreme Court decision mandates a different result, we may not "countenance the continued application in this circuit of a rule, even of our own devising, which is patently inconsistent with the Supreme Court's pronouncements." *Cox v. Dravo Corp.*, 517 F.2d 620, 627 (3d Cir.), *cert. denied*, 423 U.S. 1020 (1975). *See also McMahon v. McDowell*, 794 F.2d 100, 108 (3d Cir.), *cert. denied*, —— U.S. ——, 107 S. Ct. 473 (1986). The government contends that because of the intervening decision in *United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984), *Griffin* is no longer binding law.

In *Varig* and *United States v. United Scottish Insurance Co.*, 467 U.S. 797 (1984), decided in the same opinion, plaintiffs claimed that their injuries or damages from aircraft accidents had resulted from the negligence of the Federal Aviation Administration (FAA) and its predecessor, the Civil Aeronautics Agency (CAA), in approving aircraft designs. Congress granted the FAA authority to exercise its discretion in promulgating regulations governing inspection and licensing of aircraft. The FAA responded with a system under which manufacturers remain responsible for testing and compiling data, while the FAA receives the data for review and retains the option of performing spot-inspections with its own staff or surrogate representatives.

In *Varig*, the FAA had inspected the Boeing 707 before issuing a type certificate approving the aircraft design, but it apparently approved the aircraft at various stages without inspecting the design of the lavatory towel disposal receptacle which did not satisfy applicable safety regulations. The failure of that receptacle to contain a fire proved fatal to 124 persons on board the Boeing 707 aircraft involved in the accident. In *Scottish*, the FAA had approved, without performing its own inspection, an aircraft modification involving installation of a cabin

heater which did not meet applicable safety regulations. That heater was the cause of a fire.

In considering the applicability of the discretionary function exception, the Court isolated two relevant factors useful in determining when the exception applies. "First, it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case". *Id.* at 813. The Court stated that the basic inquiry is whether "the challenged acts of a Government employee—whatever his or her rank—are of the nature and quality that Congress intended to shield from tort liability." *Id.* The second factor was that the exception "plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." *Id.* at 813-14. The Court noted that "Congress wished to prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." *Id.* at 814.

Applying this standard, the Court noted that what was at issue was the failure of the FAA to actually inspect the aspects of the design to which the fires were attributable. The Court construed plaintiffs' claims as challenging "the FAA's decision to implement the 'spot-check' system of compliance review, and the application of that 'spot-check' system to the particular aircraft." *Id.* at 819. The Court concluded that the FAA's implementation of a mechanism for compliance review is plainly discretionary activity because, "[w]hen an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind." *Id.* at 819-20. It followed that "the acts of FAA employees in executing the 'spot-check' program in accordance with agency directives are protected" because the FAA employees were

empowered to decide how much confidence to place in a given manufacturer's procedures. *Id.* at 820.

Following *Varig*, this court has twice questioned the continued vitality of *Griffin*. In *General Public Utilities Corp. v. United States*, 745 F.2d 239 (3d Cir. 1984), *cert. denied*, 469 U.S. 1228 (1985) (*GPUC*), the owners of the Three Mile Island nuclear facility filed an FTCA suit based on the failure of the Nuclear Regulatory Commission to investigate an occurrence at another nuclear plant and to communicate warnings based thereon. We held that the claims were barred because the Commission exercised discretion in making policy determinations to decide when occurrences were significant enough to warrant investigation and warning. *Id.* at 244-46. We rejected plaintiffs' attempted reliance on *Griffin* as "excluding professional and scientific judgments from the discretionary category" both because "*Griffin* . . . must be read cautiously because in *Varig* the discretionary exception covered an agency decision that rested on highly technical information" and because the Commission exercised discretion in making non-technical judgments as to public health and safety. *Id.* at 246.

Thereafter, in *Smith v. Johns-Manville Corp.*, 795 F.2d 301 (3d Cir. 1986), we again noted that *Griffin's* distinction between scientific evaluation and policy judgments must be read cautiously in light of *Varig*. *Id.* at 309 & n.13. In that case, defendants who were sued by present and former employees of Johns-Manville for injuries resulting from 'exposure to asbestos filed third-party claims against the United States under the FTCA based on the General Services Administration's failure to label asbestos sold to them as part of the government's asbestos disposal scheme. We rejected the third party plaintiffs' claim that the failure to warn, when isolated from the overall decision to dispose of the asbestos "as is," involved no policy judgment. We construed *Dalehite* as precluding this type of compartmentalization of agency decisions,

and concluded that, when considered as a whole, implementation of the disposal scheme required the GSA to exercise discretion to "avoid market disturbances" and "maximize the government's revenues." *Id.* at 308. Because these were policy decisions, the discretionary function exception precluded the third party claims. *Id.* at 308-09.

Although the opinions in *GPUC* and *Smith* suggest that *Griffin* must be reevaluated in light of *Varig*, we had no occasion to decide whether *Griffin* is effectively overruled, a position the government now urges us to adopt.

IV.

Does Varig require immunity for all regulatory activity?

The government has asked us to interpret *Varig* to mean that the discretionary function exception "was intended to apply to all claims arising from the regulatory activities of federal agencies." Appellant's brief at 18. Initially, the government relies on the statement in *Varig* that "whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." 467 U.S. at 813-14. In addition, the government points to this court's statement in *Smith* interpreting *Varig* as requiring that where "the challenged conduct involves the government acting in its capacity as a regulator of individual conduct, the exception presumptively applies." 795 F.2d at 307.

We do not accept this per se approach. The Fifth Circuit rejected the government's per se interpretation because it ignores the fact that "not all regulatory conduct is discretionary conduct." *Collins v. United States*, 783 F.2d 1225 (5th Cir. 1986). We agree. The plain language of *Varig* states that the exception applies only to "discretionary acts" of regulators. Our view that the

discretionary function exception is inapplicable to non-discretionary regulatory actions accords with the legislative history which indicates that the exception is "designed to preclude application of the act to a claim based upon an alleged abuse of discretionary authority by a regulatory or licensing agency. 467 U.S. at 809 (quoting Hearings on H.R. 5373 and H.R. 6463 before the House Committee on the Judiciary, 77th Cong., 2d Sess. 28, 33 (1942) (statement of Assistant Attorney General Shea)). If Congress intended to except all regulatory actions from the scope of the FTCA, we are confident it would have said no.

We do not construe the decision in *Bacon v. United States*, 810 F.2d 827 (8th Cir. 1987), as adopting a per se exception for regulatory conduct, as the government suggests. There, a group of road workers filed an FTCA action alleging negligence by the Department of Housing and Urban Development and the Environmental Protection Agency in failing to warn them of the presence of dioxin. In upholding the judgment of the United States under the discretionary function exception, the court did not rely on any per se exemption, but instead reasoned that appellants' claim was based on a failure to perform a discretionary function, i.e. to warn. *Id.* at 830.

Nor do we believe the government's broad position is supported by *Hylin v. United States*, 755 F.2d 551 (7th Cir. 1985) (*Hylin II*), *following remand from* 469 U.S. 807 (1984). In that opinion, the court directed dismissal of a complaint alleging negligence by a mine inspector in failing to discover a mine operator's non-compliance with mandatory safety regulations. The court held that the discretionary function exception precluded suit because the statute reposed discretion in the mine inspectors to determine both whether non-compliance represented an imminent danger and how and when to require compliance. *Id.* at 554.

If, as the government argues, all regulatory action is per se removed from the FTCA, there would have been no need for the *Bacon* and *Hylin II* decisions, upon which the government relies, to have focused on the discretionary nature of the regulatory acts at issue. Moreover, the post-*Varig* decisions in this circuit would not have made the same inquiry. *See, e.g., Pooler v. United States*, 787 F.2d 868, 871 (3d Cir.), *cert. denied*, —— U.S. ——, 107 S. Ct. 175 (1986) (investigator of drug distribution in a federal hospital had discretion to select, use, and control an informant); *GPUC*, 745 F.2d at 246 (applying exception because agency had discretion to weigh technical and scientific data as well as concerns with public health and safety before choosing a course of action).

Following *Varig*, several Court of Appeals cases have permitted maintenance of FTCA suits based on negligent performance of regulatory agencies, thereby implicitly if not explicitly rejecting the per se theory the government urges us to adopt. *See, e.g., Baker v. United States*, 817 F.2d 560, 565 (9th Cir. 1987); *Red Lake Band of Chepewa Indians v. United States*, 800 F.2d 1187, 1197 & n.3 (D.C. Cir. 1986); *Collins v. United States*, 783 F.2d 1225, 1229 (5th Cir. 1986).

In *Merklin v. United States*, 788 F.2d 172 (3d Cir. 1986), we made the distinction between cases where no policy judgment was implicated and the case before us there where the agency action at issue, the Atomic Energy Commission's failure to warn in connection with plant inspections, was the subject of its "unbounded" discretion in conducting plant inspections. *Id.* at 175. *See also C.P. Chemical Co. v. United States*, 810 F.2d 34, 39 (2d Cir. 1987) (exception applies because "this is *not* a case where an agency ignored its own regulations or the clear mandate of statutory procedure"); *Heller v. United States*, 803 F.2d 1558, 1563 (11th Cir. 1986) (("if a government official in performing his statutory

duties must act without reliance upon a fixed or readily ascertainable standard, the decision he makes is discretionary and within the discretionary function exception. Conversely, if there is a standard by which his action is measured, it is not within the exception") (citations and emphasis omitted). We therefore construe *Varig* as requiring the courts to distinguish between those FTCA suits based on regulatory actions which are discretionary, and which therefore cannot be maintained, and those based on alleged negligence in the performance of a non-discretionary regulatory action.

V.

Application of the Discretionary Function Exception

We must therefore address Berkovitz's contention that he has alleged negligent acts or omissions taken in violation of regulations imposing non-discretionary duties. Berkovitz's complaint alleges negligence both by DBS in licensing Lederle for manufacture of live oral vaccine using the Sabin strains, which, it alleges did not meet mandatory regulatory standards, and by FDA in approving release of a vaccine lot produced from a defective seed virus and monopool. For purposes of this decision, we need not treat separately the licensing claim and the lot release claim.

The regulations at issue here are essentially the same as those that were in effect at the time of the *Griffin* decision, where we upheld government liability for negligent approval of a production lot of a vaccine. *Compare* 21 C.F.R. §§ 601.1-601.4, 601.20, 610.1-610.2, 630.10-630.16 (1987) *with* 42 C.F.R. §§ 73.3, 73.5, 73.9, 73.70, 73.76, 73.110-73.117 (1968).[5] The government argues

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[5] In *Griffin*, we did not address the licensing claim. The district court in that case had found that the August 24, 1960 approval by the Surgeon General of the Sabin strains for use in the United States was "properly discretionary, since no regulation then in

that *Varig* undermines the *Griffin* analysis because the FDA is under no non-discretionary duty to enforce its safety regulations.

After *Varig*, it is clear that the discretionary function exception exempts the United States from claims based on 1) discretionary planning level acts and omissions, *e.g.*, *Merklin*, 788 F.2d at 174 (warning not mandatory under Atomic Energy Act); 2) discretionary operational level acts and omissions, *e.g.*, *GPUC*, 745 F.2d at 244-47 (Commission's discretionary implementation of statutory direction to review safety); and 3) non-discretionary operational level acts and omissions taken in furtherance of planning level discretionary decisions, *see Dalehite v. United States*, 346 U.S. 15, 35-36 (1953).

It is also clear after *Varig* that an agency's promulgation of a regulation specifying standards governing a matter subject to regulation does not without more make the discretionary function exception inapplicable. The necessary inquiry in such a situation is whether the agency retains the discretion whether or how to enforce that regulation. *See GPUC*, 745 F.2d at 244.

The government argues that the safety regulations governing live polio vaccine leave at least as much enforcement discretion to the FDA as the regulations at issue in *Varig* left to the FAA. For this reason, the government contends, the discretionary function exception must apply to FDA approval of polio vaccine even though we must assume for this purpose that the vaccine failed to meet substantive safety requirements set out in the FDA regulations.

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effect foreclosed such a judgment." Griffin v. United States, 351 F. Supp. 10, 26 n.20 (E.D. Pa. 1972). Because the regulations governing Lederle's licensure for production upon which Berkovitz relies were not promulgated until November 23, 1961, *see id.* at 26, the issue before us on licensing is a different one than that before the *Griffin* district court.

The regulations of the FDA and FAA are similar in the allocation of responsibility for compliance with explicit safety regulations. In *Varig*, the Court stated that the FAA certification process is founded upon the notion that "the duty to ensure that an aircraft conforms to FAA safety regulations lies with the manufacturer and operator," 467 U.S. at 816. Similarly, the FDA puts the initial responsibility for testing on the manufacturer. *See* 21 C.F.R. § 610.1 (1987) ("[N]o lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies"); 21 C.F.R. § 601.2 (1987) ("manufacturer . . . in the case of an application for a product license, shall submit data . . . which demonstrate that the manufactured product meets prescribed standards of safety"); 21 C.F.R. § 630.10(b)(4) (1987) ("[t]he neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer"); *see also* 42 C.F.R. §§ 73.3, 73.70, 73.110(b)(4) (1968).

The tests to which these regulations apply are those that Berkovitz contends the Lederle virus failed. *See* 21 C.F.R. § 630.10(b)(2) (1987) ("Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine Live Oral, unless . . . each such strain produces a vaccine meeting the safety and potency requirements of §§ 630.11, 630.15 and 630.16(b); *see also* 42 C.F.R. § 73.110(b)(2) (1968) (requiring same tests set out at 42 C.F.R. §§ 73.114(b), 73.115, 73.117). It is therefore evident that looking at the regulations as a whole, it is the manufacturer that is required to perform the tests.

Berkovitz can point to no regulation requiring the FDA to do anything. In other words, no regulation im-

poses a non-discretionary duty.[6] Berkovitz points to the statutory requirement that licenses for products may be issued:

> only upon a showing that . . . the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards.

42 U.S.C. § 262(d); *see also* 21 C.F.R. § 601.20(a) (1987) ("[a] product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this subchapter"); 42 C.F.R. § 73.5 (1968). Berkovitz contends that the FDA, unlike the FAA, is under a statutory duty to "insure" compliance with its safety regulations. Judge Higginbotham's dissenting opinion also views the statute as imposing a "clear command of federal law" because it creates a duty by the FDA to receive the showing that the vaccine manufacturer must make to the government. However, the FDA's statutory duty is not different in substance from the duty that the Supreme Court in *Varig* found rests with the FAA.

Two illustrations from the statute at issue in *Varig* will suffice to show the duty imposed on the FAA with

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[6] In *Baker*, 817 F.2d at 566, the court read 42 U.S.C. § 262(d) and 21 C.F.R. § 630.10(b)(2) as imposing on the FDA a mandatory duty to "not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted." Therefore, it held that the plaintiff's allegation of a negligent failure to require submission of test data was not covered by the discretionary function exception. Here, Berkovitz's complaint can be read as alleging a similar falure to require submission of test data. *See* App. at 30-31. We do not agree, however, that the FDA is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer. *See* 21 C.F.R. §§ 601.2, 610.1, 630.10(b)(4) (1987).

respect to receipt of the manufacturer's showing of compliance is similar to the duty on which Judge Higginbotham relies. The applicable statute provides, *inter alia*.

> The Secretary of Transportation shall make, or require the applicant to make, such tests during manufacture and upon completion as the Secretary of Transportation deems reasonably necessary in the interest of safety, including flight tests and tests of raw materials or any part or appurtenance of such aircraft, aircraft engine, propeller, or appliance. If the Secretary of Transportation finds that such aircraft, aircraft engine, propeller, or appliance is of proper design, material, specification, construction, and performance for safe operation, and meets the minimum standards, rules, and regulations prescribed by the Secretary of Transportation, he shall issue a type certificate therefor.

49 U.S.C. § 1423(a)(2). Another section provides:

> Upon application, and if it satisfactorily appears to the Secretary of Transportation that duplicates of any aircraft, aircraft engine, propeller, or appliance for which a type certificate has been issued will conform to such certificate, the Secretary of Transportation shall issue a production certificate authorizing the production of duplicates of such aircraft, aircraft engines, propellers, or appliances. The Secretary of Transportation shall make such inspection and may require such tests of any aircraft, aircraft engine, propeller, or appliance manufactured under a production certificate as may be necessary to assure manufacture of each unit in conformity with the type of certificate or any amendments or modification thereof.

49 U.S.C. § 1423(b). The Supreme Court recognized in *Varig* that "the FAA retains the responsibility for policing compliance", 467 U.S. at 816, but did not interpret

this responsibility as the type of mandate that makes the discretionary function analysis inapplicable. The Supreme Court's treatment of the discretionary function exception in the context of that statute, therefore, also governs our interpretation of the analogous FDA statute. It would be incongruous to conclude that Congress intended the FAA to exercise a lesser supervision over the safety of aircraft than the FDA was to exercise over the safety of polio vaccine, which is what the dissent appears to suggest.

In *Varig*, the Supreme Court concluded that "[t]he FAA's implementation of a mechanism for compliance review is plainly discretionary activity of the 'nature and quality' protected by § 2680(a)." 467 U.S. at 819. Reviewing the regulations at issue here, it is evident that in exercising a similar discretion, the FDA has made a policy choice to leave compliance in the first instance to the manufacturer. The FDA enters the verification process only if it exercises its discretion under the regulations to examine manufacturer data or perform its own tests. *See* 21 C.F.R. § 610.2(a) (1987) (FDA may demand samples from manufacturer for use in own testing prior to approval); 42 C.F.R. § 73.76 (1968); *see also Griffin*, 500 F.2d at 1065 n.11 (practice of DBS to perform own tests "because of the lack of reliability of the manufacturers' test results").

In the instant case, the allegations is that the FDA exercised its discretion to verify compliance and then negligently erred in finding compliance. If true, this case would be distinguishable from *Varig* where the agency failed to inspect and did not know of the noncompliance. Here the FDA allegedly discovered the defect. Berkovitz argues that once the FDA had information that the vaccine did not comply with the regulations, it had no discretion to approve either the license for production or the lot for release. There is a certain facial attraction to this

contention. On examination, however, this argument is simply that the FDA acted negligently. Indeed, Berkovitz's contention that the FDA was obliged to disapprove the noncomplying vaccine once it learned of the noncompliance is rejected by the Supreme Court's vacation of the *Hylin I* decision where the Court of Appeals had held that the discretionary function exception was inapplicable to the negligent inspection of a mine. *See Hylin v. United States* (*Hylin I*), 715 F.2d 1206, 1213-14 (7th Cir. 1983), *vacated and remanded in light of Varig*, 469 U.S. 807 (1984). On remand, the court held that notwithstanding the inspector's negligence in advising how to correct a known safety risk, the discretionary function exception applied. *Hylin II*, 755 F.2d at 553-54. As we have stated, "the issue of negligence is not relevant to the discretionary function inquiry." *GPUC*, 745 F.2d at 243.

Moreover, even if the FDA had decided to methodically examine test results or test vaccine samples itself rather than follow the FAA's decision to spot-check aircraft compliance, this would be a discretionary decision. If we were to hold that an agency's discretionary choice to test all samples subjects the United States to liability whenever in testing the agency negligently fails to recognize and remove noncomplying products, we would inhibit the agency's selection of the mechanism for compliance review. This is precisely what *Varig* instructs us not to do. It follows that when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test.

In short, Berkovitz has failed to allege a violation of a non-discretionary duty imposed on the FDA by statute or regulations and therefore the discretionary function exception applies.

IV.

Conclusion

In summary, *Griffin* isolated one regulation, looked at what appears on its face to be mandatory language, and held that in light of that mandatory language the discretionary function exception was inapplicable. We do not disturb the portions of *Griffin* that hold that an agency's violation of its own mandatory regulation is not a discretionary act. However, *Varig* instructs that a court must determine whether "the basic responsibility for satisfying [the agency's] safety standards rests with the *manufacturer*," and whether "[t]he role of the [agency] . . . is merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations." 467 U.S. at 815. We have interpreted *Varig* as requiring this determination to be made by examining agency regulations as a whole.

In light of *Varig*, it is necessary to reevaluate the holding in *Griffin*. The inquiry required by *Varig* demonstrates that the responsibility for compliance with the regulations Berkovitz alleges were violated was that of Lederle, and neither the statute nor the regulations mandate the FDA's choice of how to secure Lederle's compliance. We will therefore reverse the district court's order denying the government's motion for summary judgment and remand with instructions that the court grant that motion.

A. LEON HIGGINBOTHAM, JR., *Circuit Judge*, dissenting.

The amended complaint alleges the following: At the age of approximately two months, Kevan Berkovitz was administered the Sabin oral polio vaccine by his pediatrician. Less than one month later, this vaccine caused him to sustain a case of paralytic poliomyelitis. Among the disease's many consequences is a curvature of Berkovitz's spine as great as ninety degrees. He requires ventilatory assistance to breathe, and he has lost the use of his arms, legs and hands. These injuries are permanent.

While this is an extremely difficult case, to my view the majority's tilt ignores the clear statutory language that defines the duty of the Division of Biologic Standards ("DBS") to require the submission of test data. By not requiring the government to comply with a statute designed to insure the "safety, purity, and potency" of these drug products, the majority has expanded the discretionary function exception beyond the boundaries of any case reported to date. I respectfully dissent.

The regulations in this field place mandatory duties upon a drug manufacturer, such as Lederle, that seeks to obtain a federal license to market its drug product. First, the manufacturer must make its license application to the Director of the Office of Biologics Research and Review on the forms prescribed by regulations. 21 C.F.R. § 601.2(a) (1987). Second, such application forms must be accompanied by "data derived from nonclinical laboratory and clinical studies [that] demonstrate that the manufactured product meets prescribed standards of safety, purity and potency. . . ." *Id.* Third, where the manufacturer is seeking a license for Poliovirus Vaccine Live Oral, the data to be submitted must "establish that each [poliovirus] strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance

of neurological illness has been maintained. . . ." 21 C.F.R. § 630.10(b)(2) (1987). Fourth, the manufacturer must "demonstrate[]" the neovirulence of each seed virus used in its vaccine with data garnered in its performance of a specific series of tests. 21 C.F.R. § 630.10 (b)(4) (1987).

As the majority has recognized, "Berkovitz's complaint can be read as alleging a [negligent] failure [by DBS] to require submission of test data." Maj. typescript at 22 n.6. In addition, Berkovitz's amended complaint can be read as alleging a decision by DBS to license Lederle's manufacture of this vaccine, even though the test data submitted showed that certain monovalent virus pools had failed the required neovirulence tests.[1] Amended Complaint ¶ 19(g); Joint Appendix at 31. Notwithstanding the prescribed duties of the manufacturer outlined in the preceding paragraph, however, the majority concludes that it is within the DBS's discretion not to require even the submission of required test data, and to license the manufacture of a vaccine that has failed the required tests. This disregards the clear command of federal law:

> *Licenses . . . may be issued only upon a showing that* the establishment and *the products* for which a license is desired *meet standards*, designed to insure the continued safety, purity, and potency of such products, *prescribed in regulations*, and licenses for new products may be issued only upon a showing that they meet such standards.

42 U.S.C.A. § 262(d)(1) (West Supp. 1987) (emphasis added). Such statutory language creates, at a minimum,

[1] Thus, contrary to the majority's characterization, Berkovitz's position is *not* "simply that the FDA acted negligently." Maj. typescript at 25-26; *see, e.g.*, Brief for Appellees at 21 (DBS decided "to allow distribution to the public of a discrete live poliovirus vaccine [that] it *knew* exceeded explicit *regulatory* definitions of what is safe") (original emphasis); *id.* at 36 ("What must be accepted as true is that DBS knew that the vaccine lot in question exceeded the regulatory standard.").

a duty[2] to receive the showing that the vaccine manufacturer is, under the regulations, required to make to the government.[3] As the Ninth Circuit recognized last month,

> the Secretary may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted. *See* 42 U.S.C. § 262(d) [(1982)]; 21 C.F.R. § 630.10(b)(2) [(1987)]. Agency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data. As to that there is no discretion.

Baker v. United States, 817 F.2d 560, 566 (9th Cir. 1987). The statute also creates a governmental duty not to license a manufacturer that has shown the government that its vaccine is defective. *See Loge v. United States*, 662 F.2d 1268, 1273 (8th Cir. 1981) ("The Secretary [of Health and Human Services] has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public."), *cert. denied*, 456 U.S. 944 (1982).

The majority believes that this statutory duty is not "different in substance" from the statutory duty of the Federal Aviation Administration ("FAA") that was analyzed by the Supreme Court in *Varig*. Maj. typescript at 23. This belief rests upon a misreading of *Varig* and

[2] That this section creates non-discretionary governmental duties is certainly implied by its subsection that prohibits "interfere[nce] with any officer, agent, or employee of the [Department of Health and Human] Service[s] in the performance of any *duty* imposed on him [or her] by this section or by regulations made by authority thereof." 42 U.S.C.A. § 262(e) (West 1982) (emphasis added).

[3] By contrast, this statute creates no DBS duty to receive what the manufacture is not, by regulation, obliged to send. *See, e.g.*, 21 C.F.R. § 610.2(a) (1987) (product "[s]amples . . . may at any time be required to be sent").

the federal laws that were considered therein. As the *Varig* Court noted, "[t]he FAA certification process is founded upon a relatively simple notion: *the duty to ensure* that an aircraft conforms to FAA safety regulations *lie with the manufacturer and operator*,[4] while the FAA retains the responsibility for policing compliance." [5] 467 U.S. at 816 (footnote and emphasis added). The FAA's legal duties are limited—as the majority's "illustrations" plainly show, *see* maj. typescript at 23-24—to making, or requiring the manufacturer to make, such tests "as the Secretary of Transportation deems reasonably necessary in the interest of safety," 49 U.S.C.A. § 1423(a)(2) (West Supp. 1987), and to "mak[ing] such inspection . . . as may be necessary to assure manufacture of each unit in conformity with [its type] certificate . . . ." 49 U.S.C.A. § 1423(b) (West Supp. 1987). These statutes are not commands at all. Rather, they amount to requests for the prudent exercise of agency discretion, and they are *truly* different in substance from the statute that *prohibits* vaccine licensure by the government whenever the requisite showing has not been made.

The majority's analysis distorts the discretionary function exception by extending its immunity to a government function that simply is not discretionary. "[F]ederal officials do not possess discretion to" violate federal law.[6]

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[4] *Accord* Waymire v. United States, 629 F. Supp. 1396, 1402 (D. Kan. 1986) ("in *Varig*, the FAA made a policy decision . . . that the owner or manufacturer has the primary responsibility for inspecting the plane and for the complying with FAA regulations").

[5] The FAA's choice to fulfill this policing function by "review-[ing] the data for conformity purposes by conducting a 'spot check' of the manufacturer's work" is the discretionary function that was assessed by the *Varig Court*. 467 U.S. at 817.

[6] After carefully analyzing the Supreme Court's *Varig* and *Dalehite* opinions, Judge Bork recently noted that

> a decision cannot be shielded from liability if the decision-maker is acting without actual authority. A government official has no discretion to violate the binding laws, regulations or policies that define the extent of his [or her] official powers. An employee of the government acting beyond his [or her] authority is not exercising the sort of discretion the discretionary function exception was enacted to protect. This proposition is implied in *Varig* and *Dalehite*, and has been uniformly followed.

Red Lake Band of Chippewa Indians v. United States, 800 F.2d 1187, 1196 (D.C. Cir. 1986) (footnote omitted).

Pooler v. United States, 787 F.2d 868, 871 (3d Cir.), *cert. denied*, —— U.S. ——, 107 S. Ct. 175 (1986). Accordingly, I would affirm the judgment of the district court.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 84-2893

KEVIN BERKOVITZ, a minor by his parent and natural guardians, ARTHUR BERKOVITZ his wife, DONNA BERKOVITZ and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

MEMORANDUM OPINION

DIAMOND, J.

The plaintiffs Arthur and Donna Berkovitz (hereafter, the Parent-Plaintiffs) in their own right and on behalf of their son, Kevin Berkovitz (hereafter, Minor-Plaintiff) initiated this suit alleging that the defendant negligently permitted the manufacture, sale, and licensure of Sabin Oral Poliomyelitis Vaccine (hereafter, SOPV), which, when administered to the Minor-Plaintiff by his physician, proximately caused the Minor-Plaintiff to sustain paralytic poliomyelitis.

Presently before the court is the defendant's motion to dismiss on the ground that it is immune from liability, and in the alternative, that the plaintiffs have failed to state a claim upon which relief may be granted. For the reasons given herein, the defendant's motion will be denied.

A. *IMMUNITY*

In accordance with the Public Health Services Act, 42 U.S.C. § 216(b), the Surgeon General promulgated regulations setting forth general and specific criteria for the manufacture of SOPV.[1] The requirements include the identification of various strains of attenuated polio virus, 21 C.F.R. § 630.10(b), the administration of the strain upon a population of at least one million people, 21 C.F.R. § 630.19(b)(2), and inoculation into rabits, mice, guinea pigs and various cultures, 21 C.F.R. § 630.16(a)(105). Unless the poliovirus strains and seed virus, conform to these tests, the Secretary of Health and Human Services cannot issue a license for the propagation, a manufacture and preparation or sale of the SOPV, 42 U.S.C. §§ 262(a) and (c).

In their complaint, the plaintiffs allege that the defendant was negligent in administering the applicable regulations. More specifically, the plaintiffs allege that Lederle Labs submitted to the defendant the requisite test results. However, the tests, and the results of the tests, did not comply with the regulations. Despite the non-compliable with regulations, the defendant negligently granted the original licensure to Lederle Labs and released the lot of the SOPV which was ingested by the Minor-Plaintiff.

The plaintiffs further allege that the defendant was negligent in failing to withdraw from the market the vaccine when the defendant knew or should have known that the vaccine failed to meet the requirements of the regulations; in failing to warn and take necessary pre-

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[1] Initially, these regulations were codified under 42 C.F.R. § 73.110 *et seq.*, and were in effect when the original licensure was given to Lederle Labs, but the regulations were subsequently recodified under 21 C.F.R. § 630.10 *et seq.* Since the original regulations and the current regulations are essentially the same, for convenience, we will cite to the current regulations when discussing either set of regulations.

cautions; and in failing to require Lederle Laboratories to provide adequate warnings.

In its motion to dismiss, the defendant contends that it is immune from liability pursuant to the discretionary function exception of the Federal Tort Claims Act, 28 U.S.C. § 2680(a). The Federal Tort Claims Act (hereafter, FTCA) authorizes suits against the United States for personal injuries caused by the negligence of any employee of the United States Government while acting within the scope of his duties if a private person would be held liable to the claimant in accordance with the law of the place where the act or omission occurred. 28 U.S.C. § 1346(b). However, the FTCA does not authorize suits against the government if the alleged negligent acts arise from the execution of a statute or regulation or the performance of a discretionary function or duty. 28 U.S.C. § 2680(a). Accordingly, § 2680(a) exempts from liability: (1) those acts or omissions of government employees exercising due care in the carrying out statutes or regulations and (2) acts of discretion in the performance of governmental functions or duties whether or not such discretion is abused. *Delahite v. United States*, 346 U.S. 15 (1953).

The Supreme Court in *Delahite*, 346 U.S. 15, held that:

> [those discretionary acts or duties that cannot form the basis of a suit under the [FTCA] include more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications, or schedules of operations. Where there is room for policy judgment and decisions there is discretion.

Delahite, 346 U.S. at 35-36. (footnote omitted). Hence, according to the court in *Delahite*, the discretionary function exception exempts policy judgment decisions.

The plaintiffs contend, citing *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), that the approval of the

SOPV by the defendant contrary to the applicable regulation is not within the discretionary function exception to the FTCA. In *Griffin*, the plaintiff sustained personal injuries resulting from the ingestion of a SOPV which did not conform to the defendant's regulations. The Third Circuit concluded that the government was not immune from suit pursuant to the discretionary function exception. In reaching its decision, the court interpreted the *Delahite* definition of a discretionary function as decisions involving policy judgments as to the public interest. Applying this definition, the court found that the defendant's conduct was not immunized from judicial review as a discretionary function since the government employee's conduct in implementing agency regulations required only scientific evaluation and not the formulation of policy. *Griffin*, 500 F.2d at 1066.

The defendant denies that *Griffin* is controlling in light of the reasoning and holding in *United States v. VARIG Airlines*, 467 U.S. ——, 81 L.Ed.2d 660 (1984), and *General Public Utilities Corp. v. United States*, 745 F.2d 239 (3d Cir. 1984), *cert. denied*, —— U.S. ——, 106 S.Ct. 61 (1985), (hereafter *GPUC*). In particular the defendant contends that "the Third Circuit [in *GPUC*] made it clear that it read *VARIG* as broadly as it was written, namely, that the discretionary function exception exempts claims against federal agencies growing out of their regulatory activities." (Defendant's brief p. 22).

In *VARIG*, the court reaffirmed and further explained the *Delahite* holding. According to the Ninth Circuit, "VARIG points out [that] the exception applies when [an] agency makes a decision that is grounded in social, economic, and political policy [thereby preventing] the courts from deciding [by virtue of tort actions] the policy and political decisions that have been delegated to the agencies." *Begay v. United States*, 768 F.2d 1059, 1064 (9th Cir. 1985).

In *GPUC*, the plaintiffs, owners and operators of the Three Mile Island Nuclear facility brought pursuant to the FTCA a suit against the Nuclear Regulatory Commission (hereafter, NRC) for failing to exercise due care in discovering, analyzing and negligently approving the design and construction of the facility. In determining whether the alleged conduct of the NRC was within the protection of the discretionary function exception, the Third Circuit read the *VARIG* holding as suggesting that the discretionary function clause was to avoid the judicial second guessing of administrative decisions based upon social economic or political policy considerations. *GPUC*, 745 F.2d at 243. The court defined the proper inquiry as whether the challenge conduct is within the exception.

Having reviewed the statutory and regulatory scheme, the Court concluded that the NRC was protected by the discretionary function. According to the Court, the NRC was not performing a ministerial task but rendering a decision based upon technical and scientific evaluations coupled with concerns of public health and safety. The NRC, therefore, was acting in its role as regulator of private individual's conduct and that its decisions exemplify the underlying reason for the discretionary function exception—to prevent judicial second guessing.

In *GPUC*, the Third Circuit, in determining whether the failure of the nuclear regulatory commission to comply with the statutory requirements and regulations was within the discretionary function, instructed that *Griffin* should be read cautiously since the agency decision in *VARIG* rested on technical information. *GPUC*, *supra*. However, the court did not address the validity of *Griffin* in light of *VARIG*, *see GPUC*, 745 F.2d at 246 n.8.

While the parties have focused their attention on the validity of *Griffin*, we must apply *Griffin* to the case at bar. In *Poulis v. State Farm Fire & Casualty Co.*, 747 F.2d 863 (3d Cir. 1984), the court instructed:

> "It is the tradition of this court that the reported panel opinions are binding on the subsequent panels. Thus, no subsequent panel overrules a published opinion of a previous panel. The court en banc consideration is required to overrule a published opinion of this court."
>
> Internal Operating Procedures of the Court of Appeals for the Third Circuit, Chapter 8.C. If the courts of this court are bound by earlier panels, *a fortiorari* the district court judges are similarly bound. Recognition of hierarchical nature of the federal judiciary requires no less.

Poulis, 747 F.2d at 867. Accordingly, no matter how persuasive the arguments may be that *Griffin* is no longer valid, we are bound to apply the principles in *Griffin*. Thus, to the extent that the plaintiffs have alleged that the defendant was negligent in administering the applicable regulations, the allegations of the complaint are not within the discretionary function exception to the FTCA.

However, we believe that the defendant's alleged failure to warn and failure to withdraw the vaccine from the market are within the discretionary function exception. A decision to provide warnings to the public involves the balancing of the potential risk of harm with the public's need for such information. Similarly, a decision to withdraw from the market the vaccine requires an evaluation of the potential risk of harm. In the case before us, as in *GPUC*, these decisions encompass more than a scientific analysis of data, but an evaluation of public health and safety problems. Thus, a tort action challenging the defendant's decision not to warn or withdraw the product is the type of judicial second guessing which Congress sought to prevent by enacting the exception. *See VARIG*, 81 L.Ed.2d at 674.

Accordingly, for the aforementioned reasons we conclude that the defendant's negligent licensure and approval of the SOPV do not fall within the discretionary function exception and therefore, the defendant is not immune from liability. However, the defendant is immune from liability for its alleged failure to warn and withdraw the product.

B. *Failure to State a Claim*

The Federal Tort Claims Act provides that the law of the state in which the alleged acts occurred governs questions of liability. 28 U.S.C. § 3146; *Toole v. United States*, 588 F.2d 403 (3d Cir. 1978). In the instant matter, the plaintiffs allege, and the defendant does not dispute, that Pennsylvania law is controlling. In particular, the Minor-Plaintiff premises liability upon Pennsylvania's Good Samaritan doctrine.

Under Pennsylvania law, the Good Samaritan doctrine encompasses two theories of liability. The first theory of liability is set forth in § 323 of the Restatement of Torts which provides:

> One who undertakes . . . to render services to another which he should recognize as necessary for the protection of the other's person . . . is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking if (a) his failure to exercise such care increases the risk of harm or (b) the harm is suffered because of the other's reliance upon the undertaking.

Restatement (Second) of Torts § 323. The other theory is set forth in § 324A which provides:

> One who undertakes . . . to render services to another which he should recognize as necessary for the protection of a third person is subject to liability to the third person for physical harm resulting from

> his failure to exercise reasonable care . . . if (a) [such failure] increases the risk of harm or . . . (c) the harm is suffered because of the reliance of the other or third person upon the undertaking.

Restatement (Second) of Torts, § 324A.

Hence, in order to impose liability under these sections the negligently performed acts must increase the risk of harm or the injured plaintiff must rely upon the defendant's performing the services he has undertaken to render. *Feld v. Meriam*, —— Pa. ——, 485 A.2d 742 (1984). The failure to plead increase risk of harm or reliance by the plaintiff upon the defendant's acts has resulted in the dismissal of the complaint. *See, e.g., Patentas v. United States*, 687 F.2d 707 (3d Cir. 1982).

In the case at bar, the Minor-Plaintiff properly averred that the defendant "undertook to render services" by assuming the obligation to monitor and test SOPV before issuing the license for the manufacture or sale of the substance. Even though the Minor-Plaintiff failed to allege that the defendant's failure to exercise reasonable care increased the risk of harm or such harm was due to the Minor-Plaintiff's reliance upon the defendant, the Minor-Plaintiff's reliance upon the defendant, the Minor-Plaintiff has averred in his response to this court's order of October 30, 1985, that he intends to prove that the defendant's conduct increased the risk that he would contract poliomyelitis and that the Parent-Plaintiffs relied upon the defendant's approval of the drug when they permitted the Minor-Plaintiff to consume the vaccine.

Despite the plaintiffs' failure to plead that the defendant's conduct increased the risk of harm to the Minor-Plaintiff or such harm was due to his reliance upon the defendant's undertaking of licensing the SOPV, we will not dismiss the complaint. In *Patentas*, 687 F.2d 707, the court dismissed the complaint but noted that "the

[plaintiffs did not make] adequate allegations or proof of increased risk of harm." *Id.* at 717. Since the Minor-Plaintiff has made an offer of proof of increased risk of harm, we will deny defendant's motion to dismiss and grant the plaintiffs leave to amend their complaint.

An appropriate order will follow.

/s/ Justice Diamond
United States District Judge

Date: April 30, 1986

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 84-2893

KEVIN BERKOVITZ, a minor by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

ORDER OF COURT

AND NOW, this 30th day of April, 1986, for the reasons stated in the memorandum opinion filed this date in the above-captioned action, IT IS ORDERED that the plaintiffs are granted leave to amend their complaint; and,

IT IS FURTHER ORDERED that defendant's motion to dismiss be, and the same hereby is, denied.

/s/ Justice Diamond
United States District Judge

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IT IS FURTHER ORDERED that defendant's motion to dismiss be, and the same hereby is, denied.

/s/ Justice Diamond
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APPENDIX C

STATUTES AND REGULATIONS

§ 262 Regulation of biological products

* * * *

Regulations governing licenses

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

* * * *

§ 601.20 Product licenses; issuance and conditions.

(a) *Examination—compliance with standards.* A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this subchapter: *Provided*, That no product license shall be issued except upon a determination that the establishment standards prescribed in the regulations contained in this subchapter, applicable to the manufacture of such product.

* * * *